

Claim Rejections: 35 U.S.C. § 112

Claims 11-30 stand rejected as failing to comply with Section 112.

Specifically, the Examiner contends that there is no support for the limitation that the lancer is mounted "in" the housing in claim 1, and no support for the limitation that the second compartment is adapted to "receive and store" a lancer in claim 24.

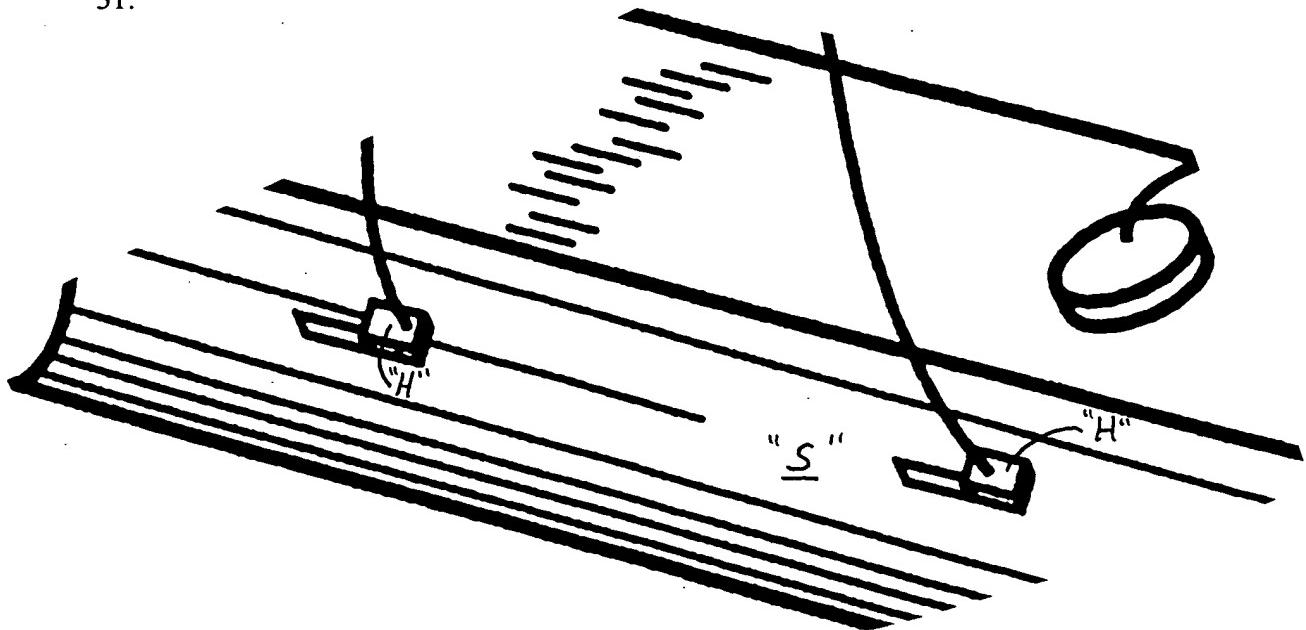
The Examiner appears to concede that, if the drawings had shown a lancer in which the locking means 31 are a pair of outwardly extending hooks, then claims 1 and 24 would have support (i.e., because the hooks would be received in the housing when securing the lancer). The Examiner asserts, however, that the application, including the drawings, lacks any disclosure that the locking means 31 are in fact hooks. With respect to the drawings, the Examiner contends that one cannot tell whether the elements 31 are outwardly extending projections or inwardly extending recesses. The Examiner also contends that the quadrilateral shape depicted for elements 31 could represent a "black box" element of unspecified structure.

The Examiner is correct that the specification does not expressly state that the elements 31 are "hooks." However, the applicants respectfully submit that a person skilled in the art would interpret the elements 31 as drawn to be outwardly projecting elements, rather than recesses, for two reasons.

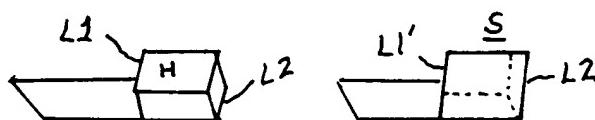
First, if the drawings are enlarged, it becomes evident that the portion of element 31 pointed to by the lead line is elevated relative to the outer surface of

the lancer. Below is a portion of Figure 2 on an enlarged scale showing the elements

31.



As drawn, the elements 31 each have a hook portion "H" which is raised from the surface "S." Had the elements 31 depicted a recess, they would have been drawn differently, as illustrated below:

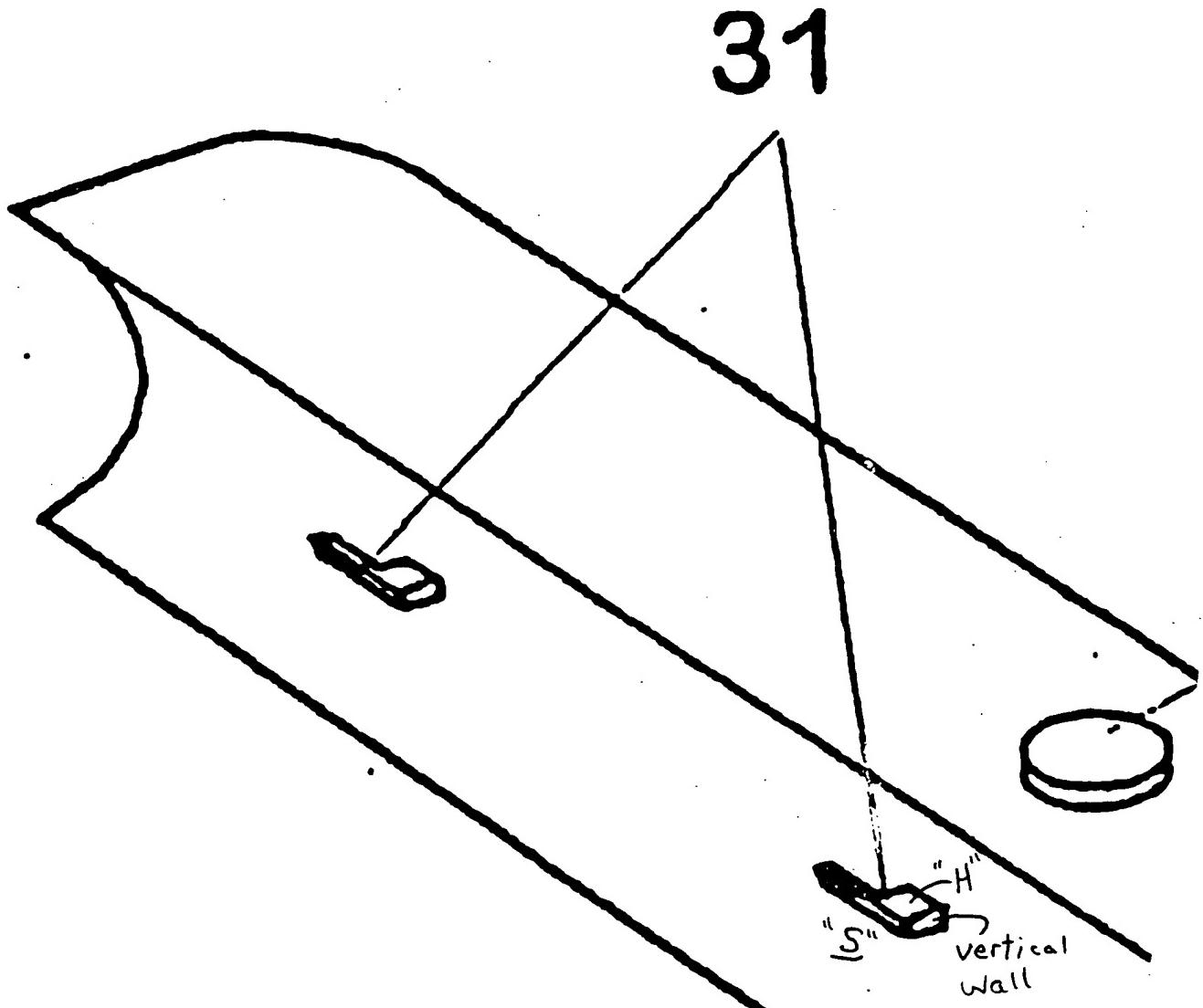


Element 31 as drawn

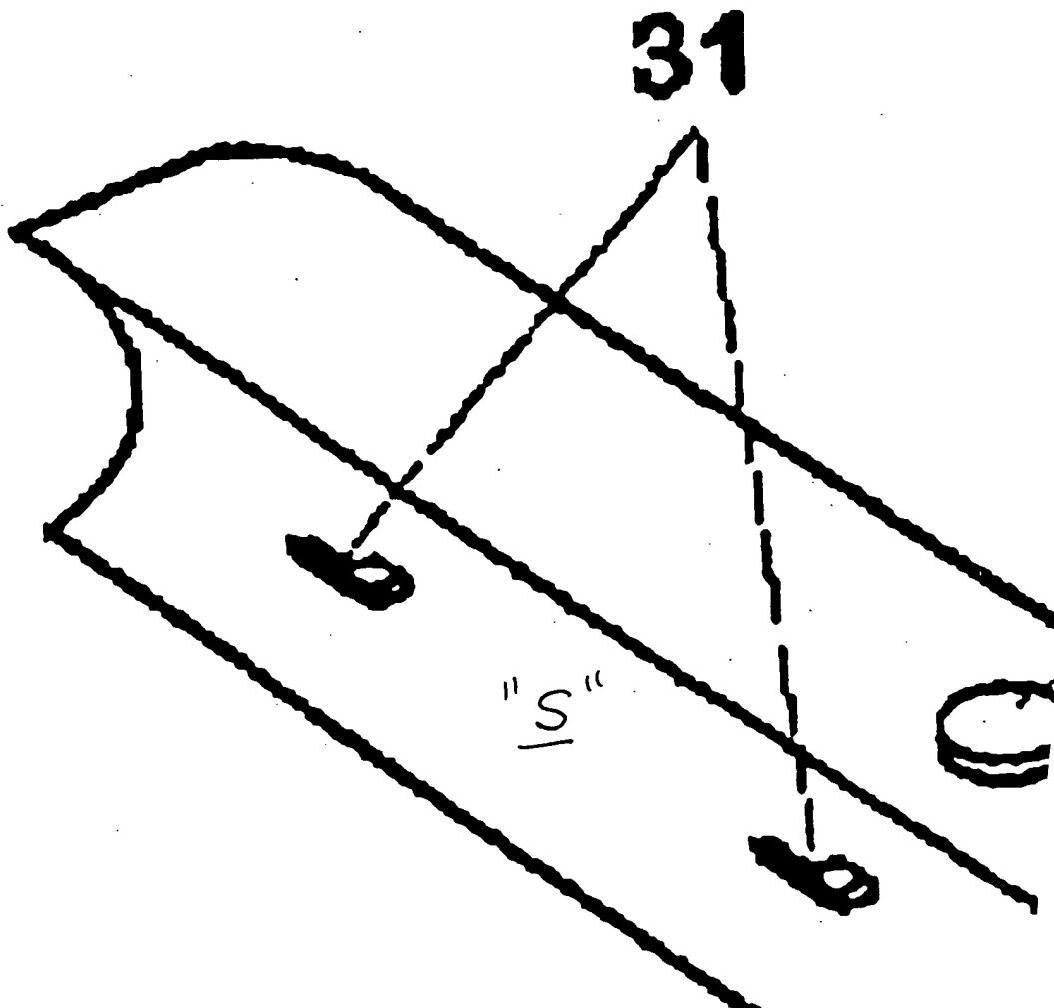
Recessed cutout

As shown above, element 31 cannot represent a recess, because lines L1 and L2 would have to be redrawn as lines L1' and L2' to properly define the outer edge of the recess. Thus, the only possible interpretation of the drawing of element 31 is that the portion "H" is elevated from the surface "S."

The original drawings filed in the parent case show the hook element "H" more clearly, as shown in the portion of original Figure 2 reproduced below:



Finally, the drawings of the priority application depict elements 31 as hooks, as shown in the portion of Figure 2 enlarged below:



The second reason why a person skilled in the art would interpret the elements 31 to be outwardly projecting is that the elements 31 are on a surface "S" which is not held when handling the lancer. If the elements 31 were recesses, then the housing would need to have outwardly projecting hooks or other elements to engage the housing and lancer. However, such hooks would be located on a portion of the

outer surface of the housing which is gripped by the user making the housing uncomfortable to hold, because the projecting elements would bite into the person's hand. For such reason, if element 31 could be interpreted as either a projecting element or a recess, a person skilled in the art would know it must be a projecting element, because it is located on the non-gripped surface.

Thus, for both reasons, namely, that the lines L1 and L2 cannot represent a recess, and because using a recess on the lancer, with the projecting element on the housing, makes no sense, the applicants respectfully submit that a person skilled in the art would interpret elements 31 to be hooks or other types of projecting locking elements.

For such reasons, the applicants respectfully request that the rejection of claims 1-30 under Section 112 be withdrawn.

Rejection Of Claim 31

Claim 31 stands rejected under 35 U.S.C. § 103(a) as obvious over Castellano et al. U.S. patent No. 5,728,074. Although Castellano does not disclose a device in which the syringe is removable, the Examiner asserts that making the syringe removable would be obvious. The Examiner cites Application of Dulberg, 289 F.2d 522 (CCPA 1961) for the proposition that, because the Castellano syringe could be made detachable, it is obvious to do so.

The Office initially made a similar assertion in the parent case, except that the cited reference was Colman et al. U.S. patent No. 5,665,065, and the author-

ity cited for the proposition that it is obvious to break up an integral device into separate components was Nerwin v. Erlichman, 168 U.S.P.Q. 177, 179 (Patent Office Bd. App. 1969). See Office Action dated January 27, 2000 in Ser. No. 09/312,796. However, as the applicants pointed out in the parent case, Erlichman cannot be read in a way which is inconsistent with Section 103 of the Patent Statute, which specifies that an applicant is entitled to a patent unless the claimed invention would have been obvious.

In the parent case, the Examiner withdrew the rejection, because Colman did not suggest a means for detachably assembling the elements. So too here, Castellano contains no suggestion of detachably coupling the syringe from the housing containing the monitor, or any suggestion of why that modification would have been desirable.

Like Erlichman, Dulberg does not support the proposition that it is obvious to modify a prior art device absent some suggestion in the art of a motivation to do so. In Dulberg, the issue was whether it would have been obvious to modify the prior art, which disclosed a cap permanently affixed to a housing, to make the cap removable. The Dulberg Court stated,

Whether a cap is made manually removable depends upon whether it is desired to gain ready access the space covered by the cap. If it were considered desirable for any reason to obtain access to the end of Peterson's holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.

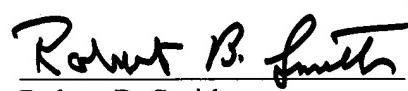
Dulberg, 289 F.2d at 523. Thus, Dulberg did not hold that it would have been obvious to make the cap removable merely because that could be done. Rather, the Court required a motivation that a person skilled in the art would want access to that space.

Here, Castellano discloses no reason why a person skilled in the art would wish to make the syringe removable from the rest of the housing. To the contrary, Castellano seeks to change the prior art practice of providing a separate syringe, injector, and blood glucose monitor, Col. 1, ll. 30-35, to make an "all-in-one device." Abstract. Because Castellano teaches away from making the syringe a separate, detachable element, it cannot properly form the basis of a finding that it would have been obvious to make such modification.

For the foregoing reasons, the applicants respectfully request that the rejection of claim 31 be withdrawn.

For the foregoing reasons, withdrawal of the rejections of claims 1-31 is respectfully requested.

Respectfully submitted,



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